DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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December 18,2014

Halyard Health (Formerly known as Kimberly-Clark Health Care)
C/O Mr. Peter Kalkbrenner
Sterilucent, Inc.
Director of Engineering
1400 Marshall Street, NE
Minneapolis, MN 55413

Re: K141712
Trade/Device Name: KIMGUARD* ONE-STEP* Sterilization Wrap (Models KC100, KC200, KC300, KC400, KC500, and KC600)
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: II
Product Code: FRG
Dated: November 19, 2014
Received: November 20, 2014

Dear Mr. Kalkbrenner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below

510(k) Number *(if known)*

K141712

Device Name

KIMGUARD* ONE-STEP* Sterilization Wrap (Models KC100, KC200, KC300, KC400, KC500, and KC600)

Indications for Use *(Describe)*

KIMGUARD ONE-STEP® Sterilization Wraps are intended to enclose another medical device that is to be sterilized by a healthcare provider using:

- Sterilucent PSD-85 Hydrogen Peroxide Sterilizer that include:
  - Lumen Cycle and
  - Non-Lumen Cycle.

KIMGUARD* ONE-STEP* Sterilization Wrap (KC100, KC200, KC300, KC400, KC500 and KC600) are intended to allow sterilization of the enclosed medical device(s) and also maintain sterility of the enclosed device(s) until used.

Test results validated that KIMGUARD ONE-STEP® Sterilization Wraps (KC100, KC200, KC300, KC400, KC500, and KC600) allowed sterilization of the enclosed devices by the Sterilucent PSD-85 Hydrogen Peroxide Sterilizer (i.e., both the Lumen and Non-Lumen Cycles). Additionally, the KIMGUARD ONE-STEP® Sterilization Wrap was validated to allow effective aeration under the pre-programmed PSD-85 Sterilization Cycles.

The PSD-85 Lumen Cycle has been validated to sterilize a load of up to ten (10) pounds (combined pouch and wrapped tray load) containing a maximum of ten (10) single channel stainless steel lumens per load with the following dimensions:

- An inside diameter of 1 mm or larger and a length of 60 mm or shorter;
- An inside diameter of 2 mm or larger and a length of 250 mm or shorter;
- An inside diameter of 3 mm or larger and a length of 350 mm or shorter.

The PSD-85 Non-Lumen Cycle has been validated to sterilize a load of up to 25 pounds (combined pouch and wrapped tray load).

All models of the KIMGUARD ONE-STEP® Sterilization Wrap (KC100, KC200, KC300, KC400, KC500, and KC600) have been validated for use with the Sterilucent PSD-85 Hydrogen Peroxide Sterilizer cycles in Table 1.

TABLE 1: Validated Sterilucent PSD-85 Hydrogen Peroxide Sterilizer Cycle
(Note: The instructions provided below are not intended to replace the detailed Instructions for Use provided with the Sterilucent PSD-85 Hydrogen Peroxide Sterilizer.)

PSD-85 Cycle	Intended Loads
Lumen	Reusable metal and nonmetal devices including devices with diffusion-restricted spaces such as the hinged portion of forceps and scissors and up to 10 single channel stainless steel lumened devices of the following dimensions per chamber load: ○ An inside diameter of 1 mm or larger and a length of 60 mm or shorter ○ An inside diameter of 2 mm or larger and a length of 250 mm or shorter ○ An inside diameter of 3 mm or larger and a length of 350 mm or shorter (Refer to the PSD-85 User Manual for complete instructions on load(s) and cycle(s), including chamber loading instructions (i.e. 10 lbs per load)
Non-Lumen	Non-lumened reusable metal and nonmetal devices including devices with stainless steel diffusion-restricted spaces such as the hinged portion of forceps and scissors. (Refer to the PSD-85 User Manual for complete instructions on load(s) and cycle(s), including chamber loading instructions (i.e. 25 lbs per load))

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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This 510(k) Summary is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Applicant's Name, Address, Telephone, FAX, Contact Person

Halyard Health (formerly known as Kimberly-Clark Health Care)
1400 Holcomb Bridge Road Roswell, GA 30076-2190, USA
Establishment Registration Number: 1033422

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DATE PREPARED:	November 19, 2014
TRADE NAME:	KIMGUARD* ONE-STEP* Sterilization Wrap (Models KC100, KC200, KC300, KC400, KC500, and KC600)
CLASSIFICATION NAME:	Sterilization Wrap
COMMON/USUAL NAME:	Sterilization Wrap
PRODUCT CODE:	FRG
DEVICE CLASSIFICATION:	Class II per 21 CFR §880.6850
PREDICATE DEVICES:	K112805 - KIMGUARD* ONE-STEP* Sterilization Wrap (Models KC100, KC200, KC300, KC400, KC500, and KC600).

INDICATIONS FOR USE

KIMGUARD ONE-STEP® Sterilization Wraps are intended to enclose another medical device that is to be sterilized by a healthcare provider using:

- Sterilucent PSD-85 Hydrogen Peroxide Sterilizer that include:
  - Lumen Cycle and
  - Non-Lumen Cycle.

KIMGUARD* ONE-STEP* Sterilization Wrap (KC100, KC200, KC300, KC400, KC500 and KC600) are intended to allow sterilization of the enclosed medical device(s) and also maintain sterility of the enclosed device(s) until used.

Test results validated that KIMGUARD ONE-STEP® Sterilization Wraps (KC100, KC200, KC300, KC400, KC500, and KC600) allowed sterilization of the enclosed devices by the Sterilucent PSD-85 Hydrogen Peroxide Sterilizer (i.e., both the Lumen and Non-Lumen Cycles). Additionally, the KIMGUARD ONE-STEP® Sterilization Wrap was validated to allow effective aeration under the pre-programmed PSD-85 Sterilization Cycles.

The PSD-85 Lumen Cycle has been validated to sterilize a load of up to ten (10) pounds (combined pouch and wrapped tray load) containing a maximum of ten (10) single channel stainless steel lumens per load with the following dimensions:

- An inside diameter of 1 mm or larger and a length of 60 mm or shorter;
- An inside diameter of 2 mm or larger and a length of 250 mm or shorter;
- An inside diameter of 3 mm or larger and a length of 350 mm or shorter.

The PSD-85 Non-Lumen Cycle has been validated to sterilize a load of up to 25 pounds (combined pouch and wrapped tray load).

All models of the KIMGUARD ONE-STEP® Sterilization Wrap (KC100, KC200, KC300, KC400, KC500, and KC600) have been validated for use with the Sterilucent PSD-85 Hydrogen Peroxide Sterilizer cycles in Table 1.

All models of the KIMGUARD ONE-STEP® Sterilization Wrap (KC100, KC200, KC300, KC400, KC500, and KC600) have been validated for use with the Sterilucent PSD-85 Hydrogen Peroxide Sterilizer cycles in Table 1.

TABLE 1: **Validated Sterilucent PSD-85 Hydrogen Peroxide Sterilizer Cycle (Note: The instructions provided below are not intended to replace the detailed Instructions for Use provided with the Sterilucent PSD-85 Hydrogen Peroxide Sterilizer.)**

PSD-85 Cycle	Intended Loads
Lumen	Reusable metal and nonmetal devices including devices with diffusion-restricted spaces such as the hinged portion of forceps and scissors and up to 10 single channel stainless steel lumened devices of the following dimensions per chamber load: o An inside diameter of 1 mm or larger and a length of 60 mm or shorter o An inside diameter of 2 mm or larger and a length of 250 mm or shorter o An inside diameter of 3 mm or larger and a length of 350 mm or shorter (Refer to the PSD-85 User Manual for complete instructions on load(s) and cycle(s), including chamber loading instructions (i.e. 10 lbs per load)
Non-Lumen	Non-lumened reusable metal and nonmetal devices including devices with stainless steel diffusion-restricted spaces such as the hinged portion of forceps and scissors. (Refer to the PSD-85 User Manual for complete instructions on load(s) and cycle(s), including chamber loading instructions (i.e. 25 lbs per load))

DESCRIPTION OF DEVICE

KIMGUARD* ONE-STEP* Sterilization Wrap is comprised of two sheets of KIMGUARD* Sterilization Wrap that is ultrasonically seamed on two edges. This seamed configuration allows for convenient wrapping of an article using two sheets simultaneously.

The sheets of sterilization wrap are square or rectangular fabric produced using a three-layer SMS (spunbound-meltblown-spunbound) process. The wrap fabric is composed of polypropylene with the addition of less than 2% by weight of phthalocyanine blue pigment, less than 1% by weight titanium dioxide pigment, and less than 0.008% by weight of anti-static treatment. The wrap allows a sterilized package to be opened aseptically.

SUBSTANTIAL EQUIVALENCE TO PREDICATE DEVICE

KIMGUARD ONE-STEP* Sterilization Wrap (i.e., subject of this Premarket Notification) is substantially equivalent to the predicate Kimberly-Clark KIMGUARD* ONE-STEP* Sterilization Wraps (K112805) in technology, design, and materials.

The following table compares the subject KIMGUARD* ONE-STEP* Sterilization Wrap to the predicate KIMGUARD* ONE-STEP* Sterilization Wrap.

DEVICE COMPARISON TABLE (TECHNOLOGICAL, DESIGN, & MATERIALS)

Characteristics	Predicate Devices: KIMGUARD* ONE-STEP* Sterilization Wrap (KC100, KC200, KC300, KC400, KC500, & KC600) (K112805)	Proposed Device: KIMGUARD* ONE-STEP* Sterilization Wrap (KC100, KC200, KC300, KC400, KC500, & KC600)
Manufacturer	Kimberly-Clark Corporation	Kimberly Clark Corporation **[SAME]**
Regulation/Product Code	Sterilization Wrap: 880.6850 / FRG	Sterilization Wrap: 880.6850 / FRG **[SAME]**
Indications for Use	The device is intended to be used to enclose another medical device that is to be sterilized by a healthcare provider by the Amsco® V-PRO™ 1 Plus Low Temperature Sterilization System's Lumen (identical to the V-PRO™ 1 Cycle) and Non-Lumen Cycles, and the V-PRO™ Low Temperature Sterilization System's Flexible Cycle. The wrap is intended to allow sterilization of the enclosed medical device(s) and also to maintain sterility of the enclosed device(s) until opened within the period of time for which performance data demonstrating maintenance of sterility has been provided. The KIMIGUARD ONE-STEP* Sterilization Wrap was validated to be effectively aerated during the pre-programmed V-PRO™, V-PRO™ 1 Plus, and V-PRO™ Flexible Cycles.	KIMGUARD* ONE-STEP* Sterilization Wrap (KC100, KC200, KC300, KC400, KC500 and KC600) are intended to enclose another medical device that is to be sterilized by a healthcare provider using: • Sterilucent PSD-85 Hydrogen Peroxide Sterilizer that includes: • Lumen Cycle • Non-Lumen Cycle KIMGUARD* ONE-STEP* Sterilization Wrap (KC100, KC200, KC300, KC400, KC500 and KC600) are intended to allow sterilization of the enclosed medical device(s) and also maintain sterility of the enclosed device(s) until used.
Sterilization Parameters	Hydrogen Peroxide-based Amsco® V-PRO™ 1 Plus Low Temperature Sterilization System's Lumen (identical to the V-PRO™ 1 Cycle) and Non-Lumen Cycles, and the V-PRO™ Low Temperature Sterilization System's Flexible Cycle	Sterilucent PSD-85 Hydrogen Peroxide Sterilizer that includes: • Lumen Cycle • Non-Lumen Cycle
Maintenance of Package Sterility	For models KC100, KC200, KC300, K400, KC500, and KC600 for at least 30 days.	Real-time testing following sterilization using Sterilucent PSD-85 Hydrogen Peroxide Sterilizer supports maintenance of package sterility for 180 days for all models of KIMGUARD* ONE-STEP* Sterilization Wrap.
Technology	Tortuous sheet material used to enclose medical devices that are to be sterilized by a healthcare provider to allow sterilization of the enclosed medical device(s) and maintain sterility of the enclosed device(s) until used.	Tortuous sheet material used to enclose medical devices that are to be sterilized by a healthcare provider to allow sterilization of the enclosed medical device(s) and maintain sterility of the enclosed device(s) until used. **[SAME]**
Device Design	Two sheets of nonwoven polypropylene fabric. Each sheet is composed of three thermally- bonded layers consisting of a Meltblown polypropylene layer surrounded by Spunbound polypropylene layers (SMS)	Two sheets of nonwoven polypropylene fabric. Each sheet is composed of three thermally- bonded layers consisting of a Meltblown polypropylene layer surrounded by Spunbound polypropylene layers (SMS) **[SAME]**

Characteristics	Predicate Devices: KIMGUARD* ONE-STEP* Sterilization Wrap (KC100, KC200, KC300, KC400, KC500, & KC600) (K112805)	Proposed Device: KIMGUARD* ONE-STEP* Sterilization Wrap (KC100, KC200, KC300, KC400, KC500, & KC600)
Method for bonding SMS layers	Thermal bonding with round pin, hexagonal, triangle bond pattern ("daisy" pattern)	Thermal bonding with round pin, hexagonal, triangle bond pattern ("daisy" pattern) **[SAME]**
Materials	Polypropylene with blue and white pigments	Polypropylene with blue and white pigments **[SAME]**
Distribution	Non-Sterile and Over-the-Counter	Non-Sterile and Over-the-Counter **[SAME]**
Single Use Device	Yes	Yes **[SAME]**

SUMMARY OF NONCLINICAL TESTS

Performance of KIMGUARD* ONE-STEP* Sterilization Wrap (KC100, KC200, KC300, KC400, KC500, KC600) has been tested in accordance with the applicable requirements recommended in *Pre-Market Notification [510(k)] Submissions for Medical Sterilization Packaging Systems in Health Care Facilities; Draft Guidance for Industry and FDA (March 7, 2002)*. All results of testing met acceptance criteria demonstrating that the KIMGUARD* ONE-STEP* Sterilization Wrap allows sterilization of contents by Sterilucent PSD-85 Hydrogen Peroxide Sterilizer and maintains sterility of contents until used.

Summary of Testing Performed	Results
Sterilucent System Sterilant Penetration	Passed
Material Compatibility/Biocompatibility - post-sterilization (Cytotoxicity- ISO Elution, ISO Intracutaneous Reactivity, ISO guinea Pig Maximization Sensitization)	Passed
Performance Testing - Post-Sterilization	Passed
Maintenance of Package Integrity (180 Days)	Passed

OVERALL PERFORMANCE CONCLUSIONS

The nonclinical studies demonstrate that the KIMGUARD* ONE-STEP* Sterilization Wrap performs as intended as a sterilization packaging system of medical devices when terminally sterilized in the Sterilucent PSD-85 Hydrogen Peroxide Sterilizer (Lumen and Non-Lumen Cycles). These studies demonstrate that the KIMGUARD* ONE-STEP* Sterilization Wrap met the same criteria as the predicate devices and are substantially equivalent.